

### **REMARKS**

Claims 7-29, 33-34, 43-46, and 48-49 are pending in this application, with claims 27-29, 33-34, 43-46 and 48-49 being under consideration. In this Amendment, claims 27 and 43 have been amended, and claims 30-31 have been cancelled.

Applicants submit that no new matter is presented herein.

Applicants respectfully request reconsideration and withdrawal of the outstanding rejections in view of the amendments set forth above, and the remarks presented below.

#### ***The Presently-Claimed Invention***

The presently-claimed invention relates, generally, to a packaged antimicrobial elastomeric article that is essentially free of powder and starch, and is coated on an outside surface with at least one antimicrobial agent. The package comprises a desiccant for reducing the relative humidity in the vicinity of the elastomeric article to less than the ambient relative humidity. The antimicrobial activity of the elastomeric article is extended compared to an unpackaged elastomeric article.

The claimed elastomeric articles beneficially minimize or reduce cross-contamination that can occur as a result of contact by a wearer or user of the article with more than one other object. When the antimicrobial agent is applied to the surface in contact with the wearer's hand, the elastomeric articles also inhibit growth of skin flora. See paragraph [0034]. The package system, which includes a moisture-resistant water-vapor impermeable barrier and a desiccant, reduces relative humidity and maintains said reduced relative humidity in the vicinity of the antimicrobial elastomeric article. See paragraph [0037]-[0038].

***Rejection under 35 U.S.C. § 103(a)***

Claims 27-31, 33-34, 43-46, 48-49 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,133,090 ("Modak") in view of U.S. Application No. 2002/0152538 ("McDevitt"), further in view of U.S. Patent No. 5,322,161 ("Shichman") and U.S. Patent No. 5,357,636 ("Dresdner").

Applicants respectfully traverse this rejection.

The Office Action relies upon Modak for disclosing an antimicrobial elastomeric article that includes anti-infective agents such as chlorhexidine salts and a lubricating agent. Additionally, the Office Action asserts that Modak discloses gloves that are essentially free of starch in Examples 3 and 4, and points out that the use of the term "powder and/or starch" has been interpreted to mean that gloves that include one of these components but not the other fall within the scope of the claims. The coating of Modak may further comprise quaternary ammonium halides such as benzalkonium chloride, and biomedically acceptable polymers such as polyurethanes and silicones. The polymers may be used to "minimize the possibility of lubricating agent being released from the glove surface and to provide lubricity due to the nature of the polymeric component." See col. 3, lines 1-4.

The Office Action admits that the anti-infective agent of Modak is not provided on the outside surface of the elastomeric article, but cites Dresdner for disclosing providing a coating on an outside surface of an elastomeric article (citing Example 1). Dresdner is also cited for disclosing sterile packaging of elastomeric gloves, and use of chlorhexidine gluconate and benzalkonium chloride as antiseptic agents.

The Office Action also admits that Modak does not disclose a process for extending antimicrobial activity.

McDevitt is cited for disclosing a finger glove that is contained in a package "...in order to preserve any additives applied to the finger glove or otherwise to maintain the finger glove in a sterile environment." See paragraph [0189].

Shichman is cited for disclosing adding a dessicant to a package to reduce moisture.

Applicants submit that the combination of Modak, Dresdner, McDevitt, and Schichman fails to disclose or suggest the presently-claimed invention for at least the following reasons.

Modak relates to an antiviral surgical or examination glove including a biguanide anti-infective agent and a lubricating agent/donning aid which is preferably a modified corn starch. See col. 2, lines 20-22. Although a suitable lubricating agent may include other powders such as zinc oxide, hydroxycellulose, or corn starch that has been blocked with benzalkonium chloride, didecyldimethylammonium chloride, or gluconic acid, Modak specifically teaches that the lubricating agent is preferably a modified corn starch. See col. 2, lines 20-22 and 51-63. The corn starch is blocked in order to prevent the anti-infective agent from being adsorbed. The anti-infective agent is provided inside the glove to protect health care workers from exposure to pathogens, such as HIV and HBV. See col. 1, lines 32-40.

In describing the process for forming gloves, Modak discloses that

After the leaching step, the inner coating was formed by dipping the leached glove into a powder slurry containing 15% cornstarch, 0.2% Bardac 2250 and 2% chlorhexidine gluconate (CHG). To form this slurry 450 g of cornstarch was suspended in water and diluted to 2700 ml deionized water, and 6 ml of Bardac 2250 was added to it and mixed well. This solution was mixed by placing on a magnetic stirrer and 300 ml of 20% CHG was added slowly and the mixing continued for 20 minutes. This slurry was then ready for use.

Finally, the CHG treated glove was dried in an oven at 100°C for 1 hour to complete the gloves, which were then removed from the forms.

See column 5, lines 9-21.

Each embodiment and example described in Modak requires that the glove be coated with a slurry containing a non-adsorbent lubricating agent (i.e., a starch or powder), and an antiviral agent. See Example 1 (slurry containing 15% cornstarch and 2% CHG), Example 2 (slurry containing 15% cornstarch and 2% CHG), Example 3 (slurry containing 5% zinc oxide powder and 1-2% CHG), Example 4 (2% hydroxyethylcellulose, optionally 1% zinc oxide powder, and 1-2% CHG), and Example

7 (8% cornstarch and 2% CHG). Even the comparative examples set forth from col. 5, line 55 to col. 6, line 60 are based on preparing gloves using slurry dip coatings containing starch and CHG. All of the slurries described in Modak contain starch or powder lubricants such as cornstarch, hydroxyethylcellulose, and zinc oxide. There is no disclosure or suggestion in Modak of gloves having antiviral inner coatings that are essentially free of powder and starch.

Powder has been routinely applied to gloves as a lubricant. See Exhibit A, excerpt from the FDA's Medical Glove Guidance Manual, pages 4-1, 8-1, 8-4, and 10-64. The process of applying a powder lubricant to a glove by forming a slurry containing the powder lubricant is well-known in the art. The process for applying powder to gloves is described briefly on page 4-1 and 4-2 of the Medical Glove Guidance Manual, and on pages 3 and 5 of the "Citizen's Petition to the Food and Drug Administration to Ban Cornstarch Powder from Gloves" (2009), which is attached as Exhibit B. The Citizen's Petition indicates that "[t]he ADP powder is purchased by glove manufacturers and added to a water slurry suspension containing additives and preservatives."<sup>1</sup> In order to coat the gloves with the powder, "[t]he unfinished glove is dipped into the powder slurry where it 'picks up' the powder." *Id.* To substantiate the fact that powder remains on the gloves as a result of such a process, Applicants have also attached as Exhibit C an abstract of an article by Chaput et al., "Evaluation of Powdered Latex Medical Gloves Using ASTM D6124-00," *Journal of Testing and Evaluation* 29(6) (2001), which indicates that commercially available powdered gloves contain from 37 to 260 mg powder per examination glove, and from 30 to 513 mg powder per glove for surgeon's gloves.

Accordingly, Applicants submit that powdered gloves, such as those prepared in Modak, contain a significant amount of powder or starch in their final form. Such gloves cannot be considered essentially free of powder and starch, as required by the presently-claimed invention.

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<sup>1</sup> ADP stands for absorbable dusting powder, i.e., cornstarch. Its preparation is described on page 3 of the Citizen's Petition.

Further, the Office Action admits that Modak does not disclose a glove that has an outer coating of anti-infective agent, and one skilled in the art would not be motivated to make this modification because Modak relates to protecting the hands of the person wearing the glove. With respect to the assertion that Dresdner remedies this deficiency because it discloses a glove having an antimicrobial coating on the outer surface, Applicants respectfully disagree.

Dresdner is directed to medical gloves that include a non-liquid antiseptic composition that is provided **between** inner and outer elastomeric layers of a glove, so that the antiseptic composition can protect the hand of the wearer from infections if the glove is punctured. See Abstract and Figure 2A. Providing an antiseptic composition sandwiched between glove layers is not the same as providing a glove having an outer antiseptic coating, and Applicants submit that one skilled in the art would not modify the glove of Modak, which has an inner antiseptic coating, to provide an outer antiseptic coating thereon based on the disclosure of Dresdner. Like Modak, the primary goal of Dresdner is to protect the hands of the person wearing the glove, not prevention of cross-contamination. Further, Applicants submit that one skilled in the art would recognize that the antiseptic composition of Dresdner that is sandwiched between glove layers would not be suitable for use on the outside surface of an elastomeric article. These distinctions are clear from the description of how to prepare such a glove that is set forth in Example 1.

Example 1 of Dresdner describes a method that includes forming a first, inner polyethylene plastic glove layer on a first glove mold, forming a second, larger, outer neoprene rubber glove layer on a second glove mold, and preparing an antiseptic composition primarily comprising polyethylene glycol and glycerin. The **inner** surface of the outer neoprene rubber glove layer is coated with the antiseptic composition, and is then slipped over the inner polyethylene glove layer (which is still on the mold) so that the antiseptic composition is provided **between** the glove layers. Once the glove has cooled and the antiseptic composition has gelled, the ends of the glove layers are sealed using a silicone-containing glue. Applicants submit that there is not even a

transitory period during which the outer surface of an elastomeric article is coated with an antimicrobial agent.

Accordingly, based on the disclosures of Modak and Dresdner, one skilled in the art would not prepare an essentially starch and powder-free elastomeric article that is coated on an outside surface with at least one antimicrobial agent.

These deficiencies are not remedied by McDevitt and/or Shichman.

McDevitt relates to a finger glove formed from a nonwoven web material that is liquid impermeable, but vapor permeable. The finger glove may also include an elastic nonwoven material to provide form-fitting properties. The finger glove of McDevitt is intended for use as an applicator or personal cleaning product, such as a swab or oral hygiene device, but there is no disclosure of a packaged elastomeric article that is essentially free of powder and starch and is coated on an outside surface with at least one antimicrobial agent.

Shichman merely discloses packages containing desiccants for preserving bioabsorbable articles, such as surgical staples and clips, and instruments that contain such articles. The articles do not incorporate antimicrobial agents, and there is no disclosure of preserving antimicrobial activity of an elastomeric article that is essentially free of powder and starch and is coated on an outside surface with at least one antimicrobial agent.

For at least these reasons, Applicants submit that one skilled in the art would not look to Dresdner, McDevitt, and/or Shichman to remedy the deficiencies of Modak with respect to the presently-claimed invention.

Applicants respectfully submit that the combination of Modak, Dresdner, McDevitt, and Shichman fails to disclose or suggest a packaged antimicrobial elastomeric article that is essentially free of powder and starch, is coated on an outside surface with at least one antimicrobial agent, and is provided in a package comprising a desiccant for reducing relative humidity in the vicinity of the elastomeric article, in order to extend the antimicrobial activity of the elastomeric article.

Nothing in the disclosures of Modak, McDevitt, and Shichman would lead one skilled in the art to modify them to arrive at the presently-claimed invention without the benefit of hindsight reconstruction based on Applicants' disclosure. Applicants therefore submit that claims 27-29, 33-34, 43-46 and 48-49 are not unpatentable over the combination of Modak, McDevitt, and Shichman, and respectfully request withdrawal of this rejection.

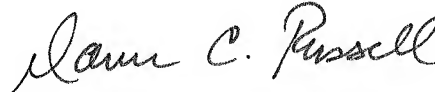
### CONCLUSION

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of claims 27-29, 33-34, 43-46 and 48-49, and the prompt issuance of a Notice of Allowance are respectfully requested.

Should the Examiner believe that anything further is necessary in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

In the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. 01-2300 referencing docket number **029714.00017**.

Respectfully submitted,



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Exhibit A - Excerpt from the FDA's Medical Glove Guidance Manual

Exhibit B - "Citizen's Petition to the Food and Drug Administration to Ban Cornstarch Powder from Gloves" (2009)

Exhibit C - Chaput et al., "Evaluation of Powdered Latex Medical Gloves Using ASTM D6124-00," *Journal of Testing and Evaluation* 29(6) (2001)